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2 IN THE UNITED STATES DISTRICT COURT  
3 FOR THE SOUTHERN DISTRICT OF NEW YORK  
4

5 -----x  
6 UMB BANK, N.A., as Trustees,  
7 Plaintiff, C.A. No.  
8 V. 15 Civ. 08725 (GBD)  
9 SANOFI,  
10 Defendant.  
11 -----x  
12

13 C O N F I D E N T I A L  
14 VIDEOTAPED DEPOSITION OF CAROLE HUNTSMAN  
15 Boston, Massachusetts  
16 May 8, 2018  
17  
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22 Reported by:  
23 MARYJO O'CONNOR, RMR, CSR  
24 JOB NO. 141699  
25

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2 Aubagio, was approved in, I believe, either  
3 October or November of 2014.

4 Q. And in that case, it was part of  
5 the normal practice of the company to assess  
6 the commercial situation, determine whether  
7 additional studies were warranted, and, if  
8 so, conduct them and seek to expand the  
9 label, correct?

10 MR. AMSEL: Objection to the form.

11 You can answer.

12 A. I think that it is typical to  
13 assess whether you want to do a study to  
14 expand the -- submit and expand the label,  
15 yes.

16 Q. When you say "typical," you would  
17 say that it is a common practice in the  
18 pharmaceutical industry?

19 A. Yes.

20 Q. And part of that, in your opinion,  
21 does that fall into what might otherwise be  
22 known as life cycle management?

23 A. Yes.

24 Q. So we'll talk about this a bit  
25 later, but what do you understand "life cycle

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2 management" to be?

3 A. It is a means by which you expand  
4 what is known about a product, whether it is  
5 analysis of studies -- additional analysis  
6 from studies that have already been done or  
7 initiating new studies.

8 Q. And life cycle management, or LCM  
9 is, again, a typical or common practice in  
10 the pharmaceutical industry?

11 A. Yes.

12 Q. And, in fact, when you were at  
13 Serono, you became aware that LCM did not  
14 just include data but could also include  
15 reformulation, for example?

16 A. Yes.

17 Q. So, for example, moving a drug  
18 from IV to sub-Q, would be an example of LCM?

19 A. Yes.

20 Q. And in some instances, that can  
21 actually have a profound implication on the  
22 commercial success of the product, correct?

23 MR. AMSEL: Objection to the form.

24 You can answer.

25 A. I think it's on a case-by-case

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2 media activity around Lemtrada also  
3 continues, with Drs. Daniel Kantor and Barry  
4 Singer tweeting live from today's oral  
5 presentation with Dr. Eva Havrdová, as well  
6 as Don Seiffert from Boston Business Journal,  
7 who tweeted that 'Lemtrada is looking  
8 increasingly like a cure for multiple  
9 sclerosis.'"

10 Do you see that? It's on the  
11 first page. It's the last sentence under the  
12 section that begins "Lemtrada." Do you see  
13 that?

14 A. Yes. Sorry.

15 Q. Were you aware of that statement  
16 at the time it was made?

17 A. No.

18 Q. And are you aware of any efforts  
19 on the part of either Sanofi or Genzyme to  
20 correct Don Seiffert?

21 MR. AMSEL: Objection to the form.

22 You can answer.

23 A. I'm not aware.

24 Q. Now, previously we were talking  
25 about Canada. So when you joined Sanofi in

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2 2012, what was your primary job assignment?

3 A. It was to build out the MS  
4 organization and prepare for the launches of  
5 both of our MS therapies in North America.

6 Q. And at the time you joined,  
7 essentially, you were given the task of  
8 building the actual commercial and marketing  
9 infrastructure for those two drugs, correct?

10 A. Yes.

11 Q. And, briefly, what does that  
12 entail?

13 A. It entails hiring and training  
14 people, developing product strategy and  
15 collateral, and taking care of all commercial  
16 aspects of launch.

17 Q. And so let's talk a little bit  
18 about that in the context of MS, because it's  
19 a little more complex in MS than it would be,  
20 say, in other drug context, correct?

21 A. I'm not sure what you mean by  
22 that.

23 Q. What is a REMS, R-E-M-S?

24 A. That's a risk evaluation and  
25 mitigation strategy.

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2 Do you see that?

3 A. Yes.

4 Q. And it identifies that one  
5 potential unmet need is "durable disability  
6 improvement." Do you see that?

7 A. Yes.

8 Q. Do you agree that that was, in  
9 fact, a new goal for an unmet need?

10 MR. AMSEL: Objection to the form.

11 A. Yes.

12 Q. And "Freedom from clinical disease  
13 activity." Do you see that?

14 A. Yes.

15 Q. That also would be an unmet need?

16 A. Yes.

17 Q. And might we now call that NEDA?

18 MR. AMSEL: Objection to the form.

19 A. Technically, I don't think it's  
20 the same definition. It's changed over time.

21 Q. But it's the same concept, right?

22 A. The concept is similar.

23 Q. And then it says below that,  
24 "Durable disability improvement progression-  
25 free survival."

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2 Q. Okay, fair point.

3 [REDACTED]

[REDACTED]

[REDACTED]

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2 is?

3 A. The what?

4 Q. CVR Agreement.

5 A. I don't -- I don't know very much  
6 about that at all.

7 Q. Were you aware of the existence of  
8 an agreement relating to the contingent value  
9 right that had been issued as part of the  
10 merger between Genzyme and Sanofi?

11 A. I had heard of it. I just heard  
12 it existed. I read some things that were in  
13 the paper, et cetera, about it. But I never  
14 had any discussion about it.

15 Q. So I don't need to show you the  
16 CVR Agreement, because you've never read it.

17 A. I've never read it.

18 Q. And if I asked you what the term  
19 "diligent efforts" meant, you couldn't tell  
20 me? In the CVR Agreement. Withdraw the  
21 question.

22 With respect to the "diligent  
23 efforts" clause in the CVR Agreement, you  
24 couldn't tell me what it is?

25 MR. AMSEL: Objection to the form

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2 of the question. Objection; calls for a  
3 legal conclusion. But you can answer it.

4 A. I've never read the CVR Agreement.

5 Q. Has anyone ever given you a  
6 summary of the CVR Agreement?

7 A. No.

8 Q. Has anyone discussed the CVR  
9 Agreement with you?

10 A. I'm aware that the CVR Agreement  
11 exists, and I'm aware that it's relevant to  
12 this ongoing case.

13 Q. Did your counsel show you the CVR  
14 Agreement?

15 MR. AMSEL: You can answer that  
16 question --

17 Q. Yes or no.

18 MR. AMSEL: -- "yes" or "no" only.  
19 Don't get into any substance of anything  
20 that --

21 Q. And how long did you spend talking  
22 to your counsel in preparation for the  
23 deposition?

24 A. Do I have any reason to --

25 MR. AMSEL: You can answer that.